

BIENNIAL MEDICAL DEVICE MANUFACTURING LICENSE RENEWAL APPLICATION**PLEASE COMPLETE THIS FORM FULLY—INCOMPLETE APPLICATIONS WILL BE RETURNED***See page 2 for instructions.*☐ NO CHANGES FROM PREVIOUS APPLICATION ☐ APPLICATION REFLECTS CHANGES OTHER THAN OWNERSHIP OR LOCATION

1. Name of Firm			9. Facility Operator (name and title)		
2. DBA (List additional DBA's on separate sheet if necessary.)			10. Facility Telephone Number ()		11. Facility FAX Number ()
3. Facility Address (number, street)			12. 24-Hour Emergency Telephone Number ()		13. E-mail Address
4. Facility Address (continued)			14. Correspondent (name and title)		
5. City	State	ZIP Code	15. Correspondent Telephone Number ()		16. Correspondent FAX Number ()
6. Mailing Address (if different from firm or P.O. Box number)			17. Country (if other than United States)		18. FDA CFN or FEI Number
7. Mailing Address (continued)			19. Web site (URL)		
8. City	State	ZIP Code	20. Interstate Commerce <input type="checkbox"/> Product Shipped <input type="checkbox"/> Product or Raw Materials Received <input type="checkbox"/> N/A		

21. Type of Ownership <input type="checkbox"/> Individual/Sole Proprietorship <input type="checkbox"/> Partnership <input type="checkbox"/> Corporation/Limited Liability Company <input type="checkbox"/> Nonprofit <input type="checkbox"/> Other: _____	
22. Corporate Name (if applicable)	State of Incorporation
23. Owners' or Officers' Names and Titles	Owners' or Officers' Names and Titles

24. Type of Manufacturing Business (check all that apply) <input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract <input type="checkbox"/> Component <input type="checkbox"/> Specification Developer <input type="checkbox"/> Other: _____	
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25. Stage of Manufacture at Date of Application (check all that apply) <input type="checkbox"/> Manufacturing Products <input type="checkbox"/> Design Development <input type="checkbox"/> Design Validation <input type="checkbox"/> Pre-production Design Transfer <input type="checkbox"/> Other: _____	
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26. Intended Device Destination (check all that apply) <input type="checkbox"/> Investigational Studies <input type="checkbox"/> Export Market <input type="checkbox"/> California Distribution <input type="checkbox"/> U.S. Distribution <input type="checkbox"/> Other: _____	
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27. Check Each Product Area that Applies to the Devices Manufactured		
<input type="checkbox"/> 862 Clinical Chemistry and Clinical Toxicology	<input type="checkbox"/> 874 Ear, Nose, and Throat	<input type="checkbox"/> 886 Ophthalmic
<input type="checkbox"/> 864 Hematology and Pathology	<input type="checkbox"/> 876 Gastroenterology/Urology	<input type="checkbox"/> 888 Orthopedic
<input type="checkbox"/> 866 Immunology and Microbiology	<input type="checkbox"/> 878 General and Plastic Surgery	<input type="checkbox"/> 890 Physical Medicine
<input type="checkbox"/> 868 Anesthesiology	<input type="checkbox"/> 880 General Hospital and Personal Use	<input type="checkbox"/> 892 Radiology
<input type="checkbox"/> 870 Cardiovascular	<input type="checkbox"/> 882 Neurological	<input type="checkbox"/> Unclassified Devices
<input type="checkbox"/> 872 Dental	<input type="checkbox"/> 884 Obstetrical and Gynecological	

28. List the types of classified and/or unclassified manufactured devices in the spaces below. Use additional sheets if necessary.			
Federal Classification Title	Classification (Check One)		
	I	II	III

29. Identify processes employed or planned in the manufacture of the devices listed above and if activities will be done in-house or by contract. Use additional sheets if necessary.

Process/Activities	In-House	Contract	Process/Activities	In-House	Contract
Sterilization			Repackaging/Relabeling		
Software Development			Remanufacturing/Refurbishing		
Circuit Board Assembly			Tissue/Cell Culture		
Lyophilization			Other:		
Antigen/Antibodies					

30. Biennial Payment Codes (Check only one code—see page 2, sec. 30) <input type="checkbox"/> A—\$2600 <input type="checkbox"/> B—\$1700		31. License Fees Due: Enter Each Fee Below:	
MAKE CHECKS PAYABLE TO: DEPARTMENT OF HEALTH SERVICES <i>See page 2 for mailing address</i>		a. License Fee (see #30)	\$
		b. Late Fee (\$10 if over 30 days late)	\$
		c. Total Payment Due	\$

The Food and Drug Branch MUST BE NOTIFIED of any change in the application information as provided by California Health and Safety Code
By signature, I declare under penalty of perjury that all information provided herein is true and correct.

32. Signature of Applicant	Printed name	Title	Date
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PLEASE DO NOT WRITE BELOW THIS LINE.

License Number	Expiration Date	Date Received	Payment Type	Amount \$
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Biennial Medical Device Manufacturing License Renewal Application Instructions

A separate application is required for each place of business. Please complete and/or amend this application as is most appropriate to your facility. Include the appropriate fee for each application as indicated in the fee schedule and make payable to: **DEPARTMENT OF HEALTH SERVICES**. This fee must accompany this application or the application cannot be processed. For renewals, penalty for failure to apply within 30 days after expiration is an additional \$10 that must be added to the renewal fee before the license is issued. Unsigned or incomplete applications cannot be processed. The following are further instructions on how to complete this application:

Renewal Applicant: Place an (X) in the box next to NO CHANGES FROM PREVIOUS APPLICATION, if your firm has already obtained a Medical Device Manufacturing License for this location under the current ownership, and you are renewing that license. **This license is non-transferable.** If your firm has changed location, ownership, or both, use application number EH 72N. If you have other changes to report, place an (X) in the box next to APPLICATION REFLECTS CHANGES OTHER THAN OWNERSHIP OR LOCATION. Any questions that do not apply to your company indicate with N/A. **Do not leave any sections blank.**

1. **Name of Firm:** Enter full name of business, corporation, company, or organization applying for licensure.
2. **DBA:** Enter any other name(s) your company is doing business as.
- 3.-5. **Facility Address:** Enter the number, street, city, state, and ZIP code for this facility location.
- 6.-8. **Mailing Address:** Enter the full mailing address if different from the facility address.
9. **Facility Operator:** Enter the full name of the person who is responsible for the manufacturing of medical devices at this facility and their title.
10. **Facility Telephone Number:** Enter daytime business telephone number of this facility.
11. **Facility FAX Number:** Enter facility FAX number.
12. **24 Hour Emergency Telephone Number:** Enter telephone number to be called in the event of an emergency.
13. **E-mail Address:** Enter facility or correspondent's email address.
14. **Correspondent:** Enter the name of the person to contact for information regarding this application and their title.
15. **Correspondent Telephone Number:** Enter the daytime business telephone number of the contact person.
16. **Correspondent FAX Number:** Enter the daytime business FAX number of the contact person.
17. **Country:** Enter the country where your facility is located if outside of the United States.
18. **FDA CFN or FEI:** Enter your U.S. Food and Drug Administration Central File Number or Federal Establishment ID if known.
19. **Web site:** Enter the web site address for your business if applicable.
20. **Interstate Commerce:** Place an (X) in the boxes that correctly describe your business' receipt or distribution of products or materials through or into interstate commerce.
21. **Type of Ownership:** Place an (X) in the box next to the appropriate legal description of the facility's ownership.
22. **Corporate Name:** Enter corporate name if applicable. Enter the state of incorporation if applicable.
23. **Owner's or Officer's Names:** List the business owners' or officers' names and titles.
24. **Type of Manufacturing Business:** Place an (X) in the box next to the type of manufacturing business conducted at this facility. Check all that apply.
25. **Stage of Manufacture:** Place an (X) in the box next to the stage of manufacture your products are in at the time of application submission. Check all that apply.
26. **Intended Device Destination:** Place an (X) in the box adjacent to the destination(s) for your manufactured products. Check all that apply.
27. **Products Manufactured:** Place an (X) in the box adjacent to each product area box that applies to the devices manufactured or to be manufactured. If the product being manufactured is not listed, check the box next to unclassified devices.
28. **Classified or Unclassified Devices Manufactured:** For each medical device product, list the federal classification name and classification category (I, II, or III) as listed in 21 CFR, Sections 862 to 892. Refer to the following web sites:
http://www.access.gpo.gov/nara/cfr/waisidx_00/21cfrv8_00.html or <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm>.
If not known or if thought to be unclassified, please provide your best description for each device. Use additional sheets if necessary.
29. **Manufacturing Processes:** Place an (X) in the column adjacent to any indicated processes to identify if they will be done in-house or contracted-out. Leave line blank if the indicated process will not be used in the manufacture of listed devices. List additional processes or methods as needed herein or on additional sheets, if necessary.
30. **Payment Codes:** Your license fee is based on the application type, products being manufactured and class of devices being manufactured. The total fee is calculated on a biennial license.

Application Type	Device Classification	Biennial Fee	Late Fee	Interval of Renewal and Fees	Payment Code
Renewal	I, II, III, Unclassified	\$2600	\$10	Biennially on renewal	A
Renewal for Special Firms*	Class I only	\$1700	\$10	Biennially on renewal	B

*** Special firms are limited to firms that produce medical devices that are classified by the federal regulations as "Class One" and have been exempted from GMP requirements, and firms that only manufacture optical lenses (spectacle lenses).**

31. **License Fee Due:** Enter appropriate fees due.
 - a. Enter license fee according to payment codes in #30.
 - b. A \$10 late fee is due if your application is over 30 days late.
 - c. Enter total payment due by adding a and b.
32. **Sign the application, print your name, print your title, and enter the date. All signatures must be original.**

MAKE CHECKS PAYABLE TO: DEPARTMENT OF HEALTH SERVICES

MAIL APPLICATION AND CHECK TO:

Regular Mail: California Department of Health Services
Food and Drug Branch - Cashier
MS 7602
P.O. Box 997435
Sacramento, CA 95899-7435

Overnight Mail: California Department of Health Services
Food and Drug Branch - Cashier
1500 Capitol Avenue, MS-7602
Sacramento, CA 95814

If you have any further questions, please contact the Food and Drug Branch, Medical Device Manufacturing Desk at (916) 650-6500 or visit our web site at: <http://www.dhs.ca.gov/fdb/>.